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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,322	04/23/2001	Long Y. Chiang	06897-006001	4062

26161 7590 09/23/2003

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BOSTON, MA 02110

EXAMINER
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CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/23/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/840,322

Applicant(s)

CHIANG, LONG Y.

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of request for extension of time and amendment a dated 6-16-03 is acknowledged.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,492,972 to Dickey et al (Dickey) or GB 2090834 (GB)

Dickey teaches the preparation of new azo compounds such as p-nitro-trifluoromethylbenzeneazo-N-b-cyanoethyl-N-hydroxyethylalanine (col. 2-3, in particular, formula on col. 3, lines 25-30). The above formula of Dickey meets the description requirement of instant aniline compound, particularly with respect to the variables W, K and A, as claimed. Dickey fails to teach pharmaceutical compositions and a pharmaceutically acceptable carrier. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the invention to prepare aqueous compositions containing the above aniline compound of Dickey. However, Dickey teaches aqueous suspension, which reads on a pharmaceutically acceptable carrier. The preamble "pharmaceutical" and the limitation "for inhibiting the growth of tumor cells" is an intended use and carry no patentable weight.

GB teaches pharmaceutically active compounds for formula I. According to the teachings of GB, the formula NR<sub>1</sub>R<sub>2</sub> reads on instant NAW. The variable R<sub>3</sub> of GB includes amino or cyano or amino carbonyl and thus meet the requirement of the instant variable K. GB also teaches pharmaceutically acceptable carrier. GB teaches the compositions containing above

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compounds for treating disorders of intermediate metabolism and not as claimed "for inhibiting tumor cells". However, as explained above, instant limitation is an intended use that does not carry patentable distinction. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a pharmaceutical composition containing aniline compounds with the claimed attachments from the teachings of GB with an expectation to use it for treating intermediary metabolic disorders.

***Claim Rejections - 35 USC § 112***

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

All rejected claims are drawn to the methods of inhibiting the growth of tumor cells with the administration of the instant composition. The nature of the invention is extremely complex in that it encompasses a number of tumors or metastasis conditions and inhibiting the growth of the tumors, which involves the treating and preventing the tumors. The complex nature of the claims is exacerbated by the breadth of the claims. The claim encompasses prevention as well as treatment of tumors that may or may not have been addressed in the specification, by the administration of the composition. The state of the art does not recognize the administration of

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compositions to inhibit the growth of all types of tumors using a single compound. The guidance given by the specification on how to inhibit the growth of different types of tumors is absent.

While the instant specification describes in vitro inhibition of murine sarcoma cells, the specification does not provides any guidance as to how to extrapolate the same to other tumors in vivo, in situ or to other animals, birds or human. The specification also fails to teach if the treatment is effective in completely inhibiting the tumor cell growth. The instant example only provides a 40% reduction in the growth of tumor cells, which is not a complete inhibition. Thus, the specification lacks guidance and also provides no evidence that the instant composition is effective for inhibiting the growth all types of tumor cells and whether the administration of the instant composition is effective in inhibiting the growth of a tumor cell at any stage of the tumor i.e., early or late stages. The lack of significant guidance from the specification or prior art with regard to completely inhibition of tumor cell growth with the administration of the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the tumor progression. Therefore, the practitioner would turn to trial and error experimentation to make/use the instant compositions for inhibiting the growth different types of tumor cells, at different stages of growth cycle, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
September 22, 2003